REMARKS

Interview Summary

The inventor Stephen Mamchur and applicant's representative Michael Schiff came to the Patent Office on May 12, 2010 to have an interview about this application. Present were Examiner Nathan W. Schlientz, Examiner Johann Richter, Examiner John Pak, and Examiner Johnny Riley.

Applicant and his representatives are grateful to all the Examiners for coming to the interview and offering so many helpful suggestions about how to address the concerns raised in the last Office Action and in the Advisory Action. Applicant and his representatives appreciate the good will that was apparent at the interview, and offer this Amendment in the same spirit.

Applicant and his representatives are also grateful for the undertaking made at the interview that this 37 CFR § 1.116 Amendment will be considered on its merits without a Request for Continued Examination, that further Declarations under § 1.132 will be considered for entry into the file, and that the Office will subsequently allow the case or mail a further Advisory Action.

Stephen Mamchur gave a demonstration of his invention. He presented an illustration of how his pharmaceutical compounding system and method place in the hands of the retail pharmacist the ability to provide hormone replacement therapy products that are tailored to the needs of each consumer.

Possible amendments to the claims were discussed. Applicant agreed to cancel the general system claims without prejudice. Amendments to the other claims were proposed to address all unresolved

concerns. The Examiners also asked applicant to provide evidence that estrogens could be dissolved at sufficiently high concentrations in mixtures of ethoxy diglycol and propylene glycol that were not 50:50, and in other solvents or solvent mixtures.

The amendments to the claims presented here conform to what was discussed in the interview. The information requested by the Examiners is enclosed herewith in the form of 37 CFR § 1.132 Declarations by the inventor.

The application is believed to be in condition for allowance, which is respectfully requested.

Claim amendments

The amendments to the claims presented in this paper re-word or provide additional features to the claims previously presented. Upon entry of this Amendment, claims 124, 133, 136, 138, 141 to 159, 162, 181, and 183 are all cancelled. No new claim is added. The amendments are made without prejudice: applicant reserves the right to introduce claims to the cancelled subject matter or anything else described in the application in a subsequent proceeding.

Support for the amendments is derived from the claims as previously presented. Claim 123 incorporates features previously presented in dependent claim 124, which has been cancelled. Claim 160 incorporates features previously presented in dependent claim 162, which has also been cancelled.

Renumbering of claims

Upon allowance of the application, applicant requests that the claims be renumbered such that claim 160 and its dependents come before claim 123 and its dependents.

Objections and Rejections under 35 USC § 112

Claim 146 is objected to and claims 123 and 125 stand rejected under § 112 ¶ 2 for reasons related to claim wording. Claim 146 has been cancelled. The rejection of claim 123 and 125 no longer applies to the wording currently presented.

Accompanying this response is a Second Declaration under 37 CFR § 1.132 by Stephen Mamchur. Dr. Mamchur provides written evidence from a reputable hormone supplier that three prominent naturally occurring estrogens are all soluble in dimethyl sulfoxide (DMSO) or dimethyl formamide (DMF). WO 90/11064 shows that estrogens are also soluble in a mixture of diethylene glycol monoethyl ether and propylene glycol monolaurate.

Such solvents can be used to generate concentrated solutions of estrogen(s) for use as reagents in the general compounding method of the claimed invention. Dr. Mamchur also provides experimental data showing that ethoxy diglycol and propylene glycol create an effective solvent mixture for dissolving estrogen(s) when used at various ratios. Accordingly, the skilled reader is enabled to

practice the claimed method using various mixtures of ethoxy diglycol and propylene glycol, and various other solvents or solvent mixtures.

Dr. Mamchur also explains that the 50:50 mixture of ethoxy diglycol and propylene glycol referred to in the specification and at certain places in the specification will be understood by someone skilled in the art to mean a 50:50 mixture determined by volume. He explains that there is little difference between a 50:50 mixture determined by volume, and a 50:50 mixture determined by weight, and the difference does not affect the utility of ethoxy diglycol and propylene glycol mixtures as estrogen solvents in the context of this invention.

Withdrawal of these rejections is respectfully requested.

Rejections under 35 USC §§ 102 and 103

All the claims previously pending in the application stand rejected as lacking novelty or being obvious over previously published patents and applications by Chiang (WO 90/11064), Rosenbaum (U.S. Patent 5,709,878), Carrara (WO 02/11768), and Muni (U.S. Patent 6,708,822), either alone or in combination. Applicant respectfully disagrees.

Enclosed with this Response is a first Declaration under 37 CFR § 1.132 by the inventor. Dr. Mamchur explains the following points:

- Dr. Mamchur developed his system of concentrated hormone reagent compositions to allow ordinary retail pharmacists to make pharmaceuticals that are custom tailored to the needs of each individual consumer.

- The Chiang, Rosenbaum, and Carrara references are focused on providing final products, not reagent systems.

- The Muni patent provides a kit that is intended for batch production of off-the-shelf products. A single component containing the active agent is combined with a single component which contains the excipient at a standardized ratio.

- The working examples currently sold by *Cutispharma,* the owners of the Muni patent, confirm that the Muni technology is designed for batch production. [The single mention of "individualized therapy" referred to in the Muni patent means only that different kits can provide different dosages of off-the-shelf products.]

- The Muni patent does not teach solutions containing a combination of estrogens. The estrogen combinations referred to in the patent are provided in solid form with lactose as a filler.

- None of the references suggest that active ingredients should be prepared as concentrated reagents, and then measured out in different amounts for each consumer — as claimed in the present application.

- None of the references suggest that a plurality of concentrated reagents containing different hormones can be combined together based on a consumer's particular needs — as claimed in the present application.

- Dr. Mamchur's system of concentrated reagents provides a new and effective way to address a therapeutic need that has become increasingly recognized.

- Dr. Mamchur's system has won awards in entrepreneur competitions. [This verifies both the originality and commercial importance of the claimed invention. MPEP § 2145].

The claims as amended in this Response provide a number of distinguishing features from the cited references.

Claims 123, 125, and their dependents refer to steroid hormones dissolved in a solvent mixture of ethoxy diglycol and propylene glycol. None of the references teach or suggest making hormone solutions where ethoxy diglycol and propylene glycol are used together as the primary solvents.

Claim 160 and its dependents refer to the use of concentrated hormone reagent solutions to make pharmaceutical products that are custom tailored for each consumer. As explained in Dr. Mamchur's first Declaration, none of the cited references teach or suggest the combining of more than one reagent solution, each containing different hormones, to make a pharmaceutical product of any kind. None of the cited references teach or suggest a system that allows reagents to be combined in such a way to produce pharmaceutical products that are each tailored for the needs of particular consumers.

Thus, all the claims currently presented are novel and non-obvious with respect to the cited references. The Muni patent cannot be combined with the other references under § 103 as proposed in the Office Action, because they have different objects (MPEP § 2143.01(VI)): specifically, Muni is focused on providing kits of solids and/or liquids that can be combined by the user, whereas the other references are focused on the manufacture of end-stage products with particular penetration enhancers. Nevertheless, even when combined, the references do not teach or suggest all the features of the claims as currently presented.

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

Request for interview

In the event that the Examiner determines that there are other matters to be addressed, applicant and his representatives hereby request a further interview by telephone.

Respectfully submitted,

June 10, 2010
Date

Robert M. Gamson
Reg. No. 32,986
Attorney for Applicant

CERTIFICATE OF TRANSMITTAL

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: June 10, 2010
Express Mail Label No. EH003511435US

By: Carolyn H. Bates
Carolyn H. Bates

HODES, PESSIN & KATZ, P.A.
901 Dulaney Valley Road, Suite 400
Towson, MD 21204
Phone: 410-769-6145
Fax: 410-832-5637
E-Mail: rgamson@hpklegal.com

RMG/chb
G:\files\GAMSON\MAMCHUR, Steven (Blaney McMurtry LLP)\025357.001\PTO amendment 5.docx